Pharmaceutical Management Agency Ltd v Commissioner of Patents

Court of Appeal Wellington
13, 14 October; 17 December 1999
Richardson P, Gault, Keith, Blanchard and Tipping JJ

Patents – Opposition proceedings – Swiss claims – Pharmaceutical compounds – Manner of new manufacture – Whether novelty and inventiveness resided in newly discovered purpose – Patents Act 1953, ss 2, 10, 12, 13, 14, 17, 20, 21 and 51.

The appeal involved the question of whether the Patents Act 1953 permitted the Commissioner of Patents to recognise as invention and grant a patent to protect the discovery of a new pharmaceutical use of a substance or composition already known for one or more particular medical uses. The issue arose from a change of view by the Commissioner relating to "Swiss claims", such appellation coming from the decision of the Swiss Federal Intellectual Property Office in 1984 to allow patents for claims in that form. Pharmac applied for judicial review of the Commissioner's "decision" to issue a practice note, forecasting as it did his intention to accept patent applications with claims in the Swiss form. It was accepted that to be of value the ruling of the Court should not be upon whether Swiss claims could be the proper subject-matter of a patent grant but whether a grant on such terms would meet the requirements of the Act. The High Court made declarations dismissing Pharmac's application and substantially supporting the respondents. From those declarations Pharmac appealed.

Held: There could be invention and novelty in the discovery of unrecognised properties of known pharmaceutical compounds. The obligation under international agreements to provide patent protection therefore applied and the provisions of the Patents Act were to be construed to give that effect if possible. The inventive subject-matter and novelty were in the new use for which the medicament was made (see paras [64], [65]).

John Wyeth & Brother Ltd's Application [1985] RPC 545 adopted.

Re C & W's Application for a Patent (1914) 31 RPC 235, *Re GEC's Application for a Patent* (1942) 60 RPC 1, *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252; [1960] ALR 114 and *Re Eisai Co Ltd* [1985] Official Journal EPO 64 referred to.

Wellcome Foundation Ltd v Commissioner of Patents [1979] 2 NZLR 591 (SC) approved; [1983] NZLR 385 (CA) overruled.

Appeal dismissed.

Observations: (i) Infringement depending on the state of mind or purpose of the alleged infringer is not unknown to the patent law. An example is the

exclusion from infringement for the benefit of those practising the invention for the purpose of bona fide research. There are difficulties in establishing infringement of a patented invention the novelty of which resides only in a new purpose (see paras [61], [62]).

Monsanto Co v Stauffer Chemical Co (No 1) (1984) 1 NZIPR 518, *Pfizer Corporation v Ministry of Health* [1965] RPC 261 and *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76 (HL) referred to.

(ii) The logical approach would be to permit claims to extend to the method of treatment using the compound but to require from the patentee a disclaimer of any right to sue the practitioner (see para [65]).

Other cases mentioned in judgment

Adhesive Dry Mounting Co Ltd v Trapp & Co (1910) 27 RPC 341.

Anaesthetic Supplies Ltd v Rescare Ltd (1992) 111 ALR 205; 25 IPR 119 (FCA), (1994) 122 ALR 141; 50 FCR 1 (Full Court, FCA).

Beecham Group Ltd v Bristol-Myers Co [1981] 1 NZLR 600 (CA).

Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc [1999] RPC 253.

Bristol-Myers Squibb Co v F H Faulding & Co Ltd (1998) 41 IPR 467; [1988] AIPC 37,540.

Ciba-Geigy AC (Durr's) Applications [1977] RPC 83; [1976] FSR 77.

E I Du Pont de Nemours & Co (Witsiepe's) Application [1982] FSR 303.

Hickton's Patent Syndicate v Patents and Machine Improvements Co Ltd (1909) 26 RPC 339.

Innes v Short and Beal (1898) 15 RPC 449.

Joos v Commissioner of Patents (1972) 126 CLR 611; [1972-73] ALR 831.

Mobil/Friction reducing additive (Decision G 02/88) [1990] Official Journal EPO 93; [1990] EPOR 73.

R v Patents Appeal Tribunal, ex parte Swift and Co [1962] RPC 37.

Sopharma SA's Application [1983] RPC 195.

Swift and Co v Commissioner of Patents [1960] NZLR 775.

Appeal

This was an appeal by the Pharmaceutical Management Agency Ltd (Pharmac) from the judgment of Gallen J (reported at (1998) 6 NZBLC 102,701) dismissing Pharmac's application for judicial review of a decision by the Commissioner of Patents, the first respondent. Glaxo Group Ltd and others, the second respondents, Novo Nordisk AS and others, the third respondents, and Astra AB and others, the fourth respondents, were joined in the proceeding and supported the Commissioner's decision.

Julian Miles QC, Paul Radich and *Rachael Dryden* for Pharmac.
Brendan Brown QC for the Commissioner.
Gregory Arthur and *Simon Fogarty* for Glaxo Group Ltd and others.
Clive Elliott and *Julie Balance* for Novo Nordisk AS and others.
Margaret Doucas for Astra AB and others.

Cur adv vult

The judgment of the Court was delivered by

GAULT J. [1] This appeal involves the question whether the Patents Act 1953 permits the Commissioner of Patents to recognise as invention and grant a patent to protect the discovery of a new pharmaceutical use of a

substance or composition already known for one or more particular medical uses.

[2] The issue arises from a change of view by the Commissioner. On 22 March 1990 he had issued a practice note stating:

> " 'SWISS' CLAIMS
> These are claims in the form:
>
> > The use of [known compounds] for the production of pharmaceutical compositions for the treatment of [a particular medical condition].
>
> If the compounds are new such a claim is allowable. However, if the compounds are known, and their use in pharmaceutical compositions is known, such claims are not allowable even if the particular pharmaceutical use is new. This is because the pharmaceutical composition prepared is not novel unless it is materially different from previous compositions; the fact that it is intended to be used to treat a medical condition different from that for which it has previously been used is irrelevant."

The appellation "Swiss Claims" comes from the decision of the Swiss Federal Intellectual Property Office in 1984 to allow patents for claims in this form.

[3] On 7 July 1997 the Commissioner issued the following practice note:

> "PATENT OFFICE PRACTICE NOTE
>
> 'SWISS' TYPE PATENT CLAIMS
>
> On 17 September 1990 I issued a decision (*Massachusetts Institute of Technology*, Patent Application No. 199328) in which I disallowed a claim, in the so-called 'Swiss' form, to the use of a known pharmaceutically active compound for the manufacture of pharmaceutical compositions in which the compound exhibits previously unknown therapeutic activity. I have now reviewed this practice in the light of the continuing international trend to liberalise the definition of 'invention' and have come to the conclusion that it is now appropriate that claims of the 'Swiss' type should not be refused during the examination process.
>
> Accordingly, from the date of this Practice Note, 'Swiss' type claims, of the general form:
>
> > The use, in the manufacture of a medicament, of [*the active compound*] as an active ingredient in a [*the newly invented activity*] composition in admixture with an inert carrier,
>
> or similar constructions, will not be rejected by patent examiners.
>
> Claims to therapeutic treatment of humans will continue to be disallowed, a practice confirmed by the Court of Appeal in *The Wellcome Foundation Ltd (Hitching's) Application* [1983] FSR 593. The Practice Note published on page 249 of Patent Office Journal No 1402 explains this practice in more detail.
>
> K B Popplewell
> Commissioner of Patents".

[4] The appellant (Pharmac) applied for judicial review of the Commissioner's "decision" to issue the practice note, forecasting as it does his intention to accept patent applications (undoubtedly the exercise of a statutory power of decision) with claims in the Swiss form. Pharmac is responsible for

managing the subsidisation of medicines in New Zealand and contends that the grant of patents for inventions in respect of second or subsequent pharmaceutical uses will prevent competition among pharmaceutical suppliers with adverse effects on prices.

[5] The second, third and fourth respondents are pharmaceutical manufacturers (and their industry representative organisation) who engage in research for new products and new uses for known substances and compositions and who seek patent protection for the successful results of that research. They were joined in the proceeding and support the Commissioner's position. In accordance with directions those respondents limited their evidence to selected examples of the research efforts involved in the identification and testing of new therapeutic indications and the costs of bringing successful results to the market. Great importance is attached to the market exclusivity for the period of patent protection to enable recovery of the research and development expenditure. The costs involved in identifying and obtaining regulatory approvals for new pharmaceutical uses even where other uses in medical treatment are known can be high indeed. The benefits to the public from successful outcomes are no different merely because other uses may be known so that patent protection which operates as an incentive to engage in research for new pharmaceutical substances and compositions should be available similarly for the results of research into further new therapeutic uses for known substances.

[6] Pharmac contends that the industry claims are overstated and has filed affidavit evidence emphasising the obvious relationship between patent protection and prices and the public interest in securing medicines at the lowest possible cost. References are made to the discoveries of new uses for pharmaceuticals in the past without the incentive of patent protection. It is said that the availability of patent protection for drugs for new uses will lead to abuse by obtaining prolonged protection in respect of successive insignificant advances.

[7] What the extensive affidavit evidence does show is the complexity of the economics of pharmaceutical innovation and public benefits. The same may be said of the significance in these respects of the patent system internationally. The considerations are not necessarily the same for all countries. The present issue is to be decided for New Zealand but in its international context. Particular examples do not necessarily support generalisation and it is to be kept in mind that the issue for determination is the same whether the second medical use is just marginally non-obvious over the known use and is discovered towards the end of a lengthy period of lucrative marketing of substantially the same product or, on the other hand, is a breakthrough in the treatment of a serious and widespread disease resulting from extensive research on a substance the first pharmaceutical indication of which was never patented and never brought to the market.

[8] The patent system rests on the policy that a limited-term monopoly will be granted as an incentive to innovation but subject to the invention and the best method of carrying it out being disclosed and made available for public use at the end of the term of protection. There is no assurance that regulatory approvals to market will be available nor of commercial success. The invention may well be superseded before the expiry of the patent term. Only on a

short-term and narrow perspective can that be regarded as restrictive of competition. To the extent that it is, in the area of immediate relevance, Pharmac's purchasing power presents a considerable offset.

[9] When the matter came before Gallen J in the High Court [reported at (1998) 6 NZBLC 102,701] he referred to the evidence and the competing claims for public utility and concluded that "the two positions in this regard may be said to be equally supportable". That was a broad assessment. It is unnecessary to attempt to reach any similar overall conclusion. The competing contentions are to be taken into account to the extent that they may be relevant in the examination of the law which must be undertaken.

[10] The starting point is the statute. It provides for the grant of letters patent by the Commissioner of Patents for "Inventions" which are defined as follows:

> "Invention" means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention (s 2(1)).

[11] An applicant for the grant of letters patent must file a complete specification, the requirements for which are set out in s 10(3) and (4):

> (3) Every complete specification –
> (a) Shall particularly describe the invention and the method by which it is to be performed; and
> (b) Shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
> (c) Shall end with a claim or claims defining the scope of the invention claimed.
>
> (4) The claim or claims of a complete specification must relate to a single invention, must be clear and succinct, and must be fairly based on the matter disclosed in the specification.

[12] The application is referred to an examiner who is required to report:

> (2) If the examiner reports that the application or any specification filed in pursuance thereof does not comply with the requirements of this Act or of any regulations made thereunder, or that there is lawful ground of objection to the grant of a patent in pursuance of the application, the Commissioner may either –
> (a) Refuse to proceed with the application; or
> (b) Require the application or any such specification as aforesaid to be amended before he proceeds with the application (s 12(2)).

[13] Examination will include consideration of whether or not what is claimed is an invention. In addition the examiner is to inquire into the novelty of the invention. That is whether or not the claimed invention is anticipated by prior publication or prior claiming (ss 13 and 14).

[14] If the application is in order it is accepted and advertised (s 20). Within the prescribed time any person interested may oppose the grant on grounds (inter alia) that the invention as claimed has been previously published or claimed, is obvious and clearly does not involve any inventive step having regard to what has been published or used, or that the subject of any claim is not an invention (s 21). After grant, lack of novelty, obviousness and lack of inventive step are grounds on which the patent may be revoked.

[15] At the examination stage the application should be allowed to proceed unless on no reasonable view can it be regarded as meeting the requirements of the Act: *R v Patents Appeal Tribunal, ex parte Swift and Co* [1962] RPC 37. Before Gallen J and in this Court it was accepted that to be of value the ruling of the Court should not be upon whether it is reasonably arguable that Swiss claims could be proper subject-matter of a patent grant but whether a grant on such terms in fact would meet the requirements of the Act. The application to the Court has been treated not as for judicial review but as analogous to a procedure under the Declaratory Judgments Act 1908. The Judge eventually made declarations as follows:

1. A declaration is made that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient, provided the requisite novelty (which can be in the intended second or subsequent therapeutic use) can be found.
2. A declaration is made that the decision of the first defendant that claims of the Swiss-type should not be refused during the examination process as set out in the first defendant's practice note dated 7 January 1997 is upheld and the application for review of the first defendant's issuance of the practice note is dismissed.

[16] The Patents Act says nothing about the patentability of inventions directed to medical uses nor about the form claims must take. The background against which Swiss-type claims are to be considered is to be found in the case law. In particular it has been held that there can be no grants of patent protection for methods of medical treatment of humans. The decision of this Court in *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 overruled a decision of Davison CJ, [1979] 2 NZLR 591, in which he allowed to proceed an application claiming a process for the use of known pharmaceutical compounds for the new purpose of treating or preventing meningeal leukemia or neoplasms in the brain.

[17] The effect of the decision in the *Wellcome* case is that it is not permissible to claim the new medical use of a known compound or substance. The Swiss form of claim has been devised to avoid claiming the method of treatment but to secure protection for use of the known compound or composition in the preparation of a medicament for the new medical use. The difficulty is that the newly discovered use which cannot be claimed represents the inventive subject-matter and is where the novelty resides. It is said that by constructing the claim so as to refer to the purpose for which the medicament is made the applicant is able to invoke the novelty of the new use without claiming a method of treatment. It leaves the medical practitioner free to use the medicament without infringing the claim, yet gives protection for the innovation by furnishing the inventor with the ability to restrain the manufacture of the medicament for that purpose. Continued use for any other purpose of the substance or composition remains unaffected.

[18] For the industry respondents it was submitted that should we decide that the exclusion from protection of methods of medical treatment means inventions based on second or subsequent medical use cannot be protected, we should reconsider the decision in the *Wellcome* case in the light of

developments since it was decided. Whether or not we should go that far, the reasons underlying the decision are relevant to the issue of whether there can be protectable inventions in second medical use discoveries.

[19] It is necessary to go back to the definition of "Invention" which invokes s 6 of the Statute of Monopolies 1623 (UK). That statute banned all monopolies except those for inventions. The exception (in a modern English version) is as follows:

> VI. Provided also . . . that any declaration before mentioned shall not extend to any letters-patent and grants of privilege, for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters-patent or grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.

[20] Two matters arise from this proviso. First it tells us nothing of the requirements for a manner of new manufacture to qualify within the exception. Secondly, it is not clear how much of the proviso (if anything) beyond the term "manner of new manufactures" as construed in its context is incorporated into our statutory definition of "invention". It has been doubted whether it forms part of our definition of "invention" that the manner of new manufacture "be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient": Blanco White, *Patents for Inventions* (4th ed, 1974) para 1-212. There is some support for this view in the fact that when the Patents Act was passed in 1953 it included also in s 17(1)(b) the power for the Commissioner to refuse an application if it appeared to him:

> (b) That the use of the invention in respect of which the application is made would be contrary to law or morality.

[21] It is a tribute to judicial ingenuity that the concept of "manner of new manufactures" served as the basis for the patent law throughout British law countries accommodating the advances in technology from 1623 without the need for legislative intervention until the United Kingdom in 1977 came to harmonise its laws with the Convention on the Grant of European Patents (the European Patent Convention) (Munich, 5 October 1973) (the EPC). The development of the concept of manner of new manufactures being eligible for monopoly protection for inventions under the Statute of Monopolies was traced in the judgment of the Full Court of the High Court of Australia sitting on appeal from the Deputy Commissioner of Patents in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252. That decision is heavily relied upon by the present respondents.

[22] The judgment of the Court, in tracing the development of the concept of "manner of new manufactures" said at p 271:

> "The truth is that any attempt to state the ambit of s 6 of the *Statute of Monopolies* by precisely defining 'manufacture' is bound to fail. The purpose of s 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when

science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept."

And at p 269:

"It is of the first importance to remember always that the *Patents Act* 1952-1955 (Cth), like its predecessor the *Patents Act* 1903 (Cth) and corresponding statutes of the United Kingdom (see the *Patents, Designs and Trade Marks Act* 1883, s 46; the *Patents Act* 1907, s 93; and the *Patents Act* 1949, s 101), defines the word 'invention', not by direct explication and in the language of its own day, nor yet by carrying forward the usage of the period in which the *Statute of Monopolies* was passed, but by reference to the established ambit of s 6 of that Statute. The inquiry which the definition demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the *Statute of Monopolies*. One may remark that although the Statute spoke of the inventor it nowhere spoke of the invention; all that is nowadays understood by the latter word as used in patent law it comprehended in 'new manufactures'. The word 'manufacture' finds a place in the present Act, not as a word intended to reduce a question of patentability to a question of verbal interpretation, but simply as the general title found in the *Statute of Monopolies* for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed. It is therefore a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture?' It is a mistake which tends to limit one's thinking by reference to the idea of making tangible goods by hand or by machine, because 'manufacture' as a word of everyday speech generally conveys that idea. The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?' "

[23] It is unnecessary to repeat the account of the ways in which the Courts over the years have flexibly and more broadly construed the concept to accommodate innovation in new fields of technology. The immediate significance of the decision in the *NRDC* case is in its rejection of the requirement for invention of the production, improvement, preservation or restoration of a "vendible product" which had strongly influenced judicial decisions since its articulation by Morton J in *Re GEC's Application for a Patent* (1942) 60 RPC 1. In the *NRDC* case it was held that a method of eradicating or controlling weeds from certain growing crops by applying a known herbicide toxic to weeds but not to the crop was held to be patentable. That decision was followed in England by the Court of Appeal in *Ciba-Geigy AG (Durr's) Applications* [1977] RPC 83 at p 88.

[24] The determination that a method of treatment of a horticultural crop can constitute invention proved of major significance. It undermined what had been the major reason for the exclusion from patentability of methods of treating

humans – that they did not constitute inventions: *Re C & W's Application for a Patent* (1914) 31 RPC 235 at p 236. There followed a stream of cases favouring protection for methods of treatment including treatment of the human body for other than the treatment or alleviation of illness or disease but extending to contraceptive, cosmetic and similar treatments.

The developments are reflected in the Commissioner's present practice as set out in a practice note issued in October 1998 as follows:

> "The Office currently allows claims to methods for the treatment of humans except where the treatment identified relates to the treatment of illness or disease.
>
> This practice, which must be read in conjunction with the decision in *The Commissioner of Patents v The Wellcome Foundation Ltd* [1983] FSR 593, allows some treatment of humans and would appear to include claims to the treatment of conditions that do not cause suffering or which might be matters of choice.
>
> Thus it appears reasonable to allow claims to the treatment of humans in situations including the following:
>
> - The human is not ill.
> - The condition is part of a continuum from one extreme to another, with society or medical personnel arbitrarily deciding that variation from a mean is somehow an illness. Examples include baldness, precocity, hirsutism, infertility, obesity, skin atrophy, ageing, inhibiting or increasing appetite, fertilisation, dental hypersensitivity. Also included are conditions due to dryness or oiliness of skin such as dry skin, dandruff and acne.
> - Elective treatments not in themselves illnesses. Examples include reducing the desire to smoke, methods of contraception, preventing bleeding associated with menses.
> - Diagnostic testing not requiring surgery.
> - Treatment of conditions not requiring treatment of the human. For example inhibiting toxic shock syndrome by killing the bacteria producing the syndrome on body surfaces; and treatment of lice on the body, not being a treatment of the human itself.
> - Treatment of minor conditions where the active ingredient is incorporated and available in over-the-counter proprietary products. For example treatment of teeth where the active ingredient is incorporated in toothpastes or mouthwashes for conditions such as removing plaque, etc.
> - Health and hygiene. Where the effect is to improve these areas, excluding medical treatment. The products may be found on health counters in supermarkets and included might be herbal remedies, vitamins, methods of reducing or controlling cholesterol levels in blood, calcium adsorption.
>
> These guidelines are not complete and the list is not exhaustive."

[25] New methods of treatment of animals (other than humans) also are allowed: *Swift and Co v Commissioner of Patents* [1960] NZLR 775.

[26] More recent decisions referring to the exclusion from patentability of methods of treatment of illness or disease in humans no longer give as the reason that they do not constitute "invention". The English cases (before 1977)

tended to rest on inference from the presence in the Patents Act 1949 of provisions for compulsory licences in respect of patented inventions of substances for use in medicine without also including methods of medical treatment. The same provision was enacted as s 51 of the New Zealand Patents Act 1953. The other reason resorted to was based on the wording in s 6 of the Statute of Monopolies which excluded inventions "generally inconvenient." The judgments of this Court in the *Wellcome* case include such references. But as already mentioned, there is doubt as to whether that part of s 6 was incorporated into the definition of invention in view of the enactment of s 17(2). Section 51 was repealed in 1992. Section 17 was amended in 1994 and subs (2) was repealed. The substituted section still empowers the Commissioner to refuse an application for an invention the use of which "would be contrary to morality". Therefore, it seems that the exclusion from patentability of methods of medical treatment of humans is now supported only on ethical grounds. Yet patents are granted for pharmaceutical and surgical products.

[27] As Davison CJ concluded in the *Wellcome* case, there is little logic in maintaining the exclusion. But this Court took the view that any change to the law in this respect should come from the legislature. Since that decision, Gummow J at first instance ((1992) 25 IPR 119) and a Full Court of the Federal Court of Australia (*Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 122 ALR 141) by majority have held that the Australian Patents Act 1990 (which is materially the same as our Act) does permit the grant of patents for methods of treatment of human beings: see also *Joos v Commissioner of Patents* (1972) 126 CLR 611. A contrary view taken by Heerey J in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467 is, we were told, on appeal.

[28] These developments notwithstanding, we have considerable sympathy for the view that individual medical practitioners should not be constrained in the practice of their art in the treatment of illness and disease by concerns that procedures they might adopt in the interests of their patients might render them vulnerable to proceedings for patent infringement. That is a widely-held view. In the United States, where patents for methods of medical treatment were allowed, though it seems not frequently sought until recently, steps have been taken to protect medical practitioners from infringement liability in certain circumstances. In Europe, the European Patent Convention, art 52(4) excludes from patentability an invention of a method of treatment by surgery or therapy or of diagnosis. Article 27:3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights 1996 (the TRIPs Agreement) to which New Zealand is a party, and which triggered amendments to the Patents Act in 1994, provides that member countries may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

[29] What emerges from this is that it no longer can be said that a method of treating humans cannot be an invention. To the extent that the judgments in *Wellcome* express that view we depart from them. The exclusion from patentability of methods of medical treatment rests on policy (moral) grounds. The purpose of the exclusion is to ensure that medical practitioners are not subject to restraint when treating patients. It does not extend to prevent patents for pharmaceutical inventions and surgical equipment for use in medical treatment. It is against that background that the present issue is to be determined. Can invention in the discovery of a new pharmaceutical use be protected in such a way as to leave unrestrained the medical practitioner in the practice of his or her diagnostic, therapeutic or surgical methods? In Europe the

Swiss-type use claim serves as the means of achieving such protection. That has its basis in provisions different from those in our Patents Act. The EPC requires as a condition of patentability that an invention is "susceptible of industrial application" but excludes as not so susceptible methods of treatment (art 52(4)). It then provides that this does not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in a method of treatment. Clearly pharmaceuticals are patentable. To this point there is no material difference from New Zealand law. There is then the significant provision (art 54(5)) dealing with novelty in the case of inventions of a first pharmaceutical use of a known substance or composition. It reads:

> "5. The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art."

[30] This permits a "purpose-limited" product claim. That it is confined to the substance or composition in its first pharmaceutical use is apparent from the words towards the end "any method". Again this does not create a situation different from that which prevails in New Zealand. The discovery of a pharmaceutical use for a known compound is claimable. A purpose-limited product claim can be directed to the pharmaceutical composition containing the compound or to the compound in a pharmaceutically pure form. The novelty is considered to lie in the fact that there has not previously been a pharmaceutical composition or a compound in pharmaceutically pure form, though the true inventive step is in the discovery of the new use. To claim the compound or the composition in terms qualifying it as "pharmaceutical" is, in effect, to claim by reference to the purpose for which the compound or composition is to be used and rests on the inventiveness of the use. When claimed in this form it could be said that the novelty equally lies in the intended use.

[31] Returning to Europe, the further step of accepting as patentable second pharmaceutical use inventions claimed in the Swiss form, is taken "by analogy". In a decision of the enlarged Board of Appeal of the European Patent Office (EPO) in *Re Eisai Co Ltd* [1985] Official Journal EPO 64 at p 66 the reasoning is set out as follows:

> "It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether any pharmaceutical use of the medicament was already known or not. It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC.
>
> The intention of Article 52(4) EPC, again as recognised by the Federal Court of Justice, is only to free from restraint non-commercial and non-industrial medical and veterinary activities. To prevent the exclusion from going beyond its proper limits, it seems appropriate to take a special view of the concept of the 'state of the art' defined in Article 54(2) EPC. Article 54(5) EPC alone provides only a partial compensation for the restriction on patent rights in the industrial and commercial field resulting

from Article 52(4) EPC, first sentence. It should be added that the Enlarged Board does not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing is expressed the alternative is excluded (*expressio unius (est) exclusio alterius*), is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention: nor can it be deduced from the legislative history of the articles in question. On this last point, after conducting its own independent studies of the preparatory documents, the Enlarged Board finds itself also in accord with the conclusion of the Federal Court of Justice.

For these reasons, the Enlarged Board considers that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient."

[Counsel have not been able to assist us with the relevant preparatory documents and, apart from those referred to in the Banks Committee Report and in the decision in *Sopharma SA's Application* [1983] RPC 195, we have no knowledge of them.]

[32] By its reasoning the Board distinguishes between the purpose-limited product claim allowed for inventions of first pharmaceuticals and the "use" claim in the Swiss form permitted in respect of subsequently discovered pharmaceutical applications. The claim is in the form directed to use of the known compound or composition in the manufacture of a medicament for the newly discovered medicinal use. The novelty is said to be found in the newly discovered use for the medicament in the same way as with first pharmaceutical use inventions. The present practice in New Zealand is to allow claims in respect of a second or subsequent pharmaceutical use invention only in circumstances in which a limited-purpose product claim is allowable – where it cannot be said the product as so limited lacks novelty. In practical terms this means that while the invention lies in the discovery of the new therapeutic use, the novelty must be found in the product. So availability of protection depends upon whether the composition or formulation for the new use happens to differ from that employed in any known use. If the formulation for administration is a tablet where previously the use has been by injection the novelty requirement is satisfied.

[33] A submission made by Mr Miles QC was that Gallen J rejected the unanimous views of the members of the Court in the *Wellcome* case that a medicament cannot be patented for a second use. That is in a sense obvious in that the Court held that no method of use in medical treatment could be patented. To the extent that the judgments go beyond that, we understand them as merely describing the then law and practice. They were not ruling on the point and were not addressing the issue of novelty presented by claims in the Swiss form.

[34] Gallen J reviewed the judgments at some length. His conclusion, which accords with our own, was:

> "It is true that there are observations in the decisions of all three members of the Court, that although it is accepted that a substance intended for use in treatment, is entitled to a protection for a first use, it is not so entitled for a second or subsequent use. That was a secondary concern of all three Judges and in no case was the concept analysed or the distinction made between methods of treatment and the protection of a substance intended to be used for such treatment. Further, the logical difficulties to which such a concept gives rise, were not explored. It follows then that this conclusion was not necessary for the determination of the case and is not necessarily concluded in favour of the position for which Mr Radich contends. Since the question is not therefore finally determined, it is appropriate to look at subsequent developments" (p 102,713).

[35] There are, however, some dicta in the judgments in that case reflecting recognition of development of the law from the early English cases which held that there could be no protection for a new use of a known substance.

[36] Cooke J, after referring to the earlier decision in *Beecham Group Ltd v Bristol-Myers Co* [1981] 1 NZLR 600 which involved approval of claims to a selection from a group of antibacterial chemicals of certain compounds having particularly desirable antibacterial activity, said at p 388:

> "But the suggestion in part of the argument for the Commissioner that a discovery of a new use for a known product cannot provide a basis for a grant must, in its bald form, be rejected as outmoded."

[37] Somers J at p 400 considered the claimed use not to be a new use being but a kind of therapy not so far removed from that previously known as to involve inventiveness (which is contrary to what we are asked to assume in the present case). But for that, he too appears to have recognised that the *NRDC* and selection cases found inventiveness in the discovery of previously unknown properties of known substances. He also referred to the 1977 UK Act and noted at p 404:

> "The qualification about novelty expressed in the European Patent Convention and the Patents Act 1977 – that a first therapeutic use of a known substance does not deny novelty – may not be much removed from the principles discussed in the [*NRDC*] case mentioned above."

[38] The step necessary to render Swiss-type claims acceptable would be to recognise what is in fact the situation, that the novelty as well as the inventiveness resides in the newly discovered purpose for which the medicament is to be used. That is the step the enlarged Board took "by analogy" in the *Eisai* case.

[39] For Pharmac Mr Miles submitted that an extension of the law of patentability of this kind should be left to the legislature for the same reasons as appealed to this Court in the *Wellcome* case. He argued that there are wide commercial, economic, ethical and social considerations which the Court is not equipped to investigate and assess. While that would have much greater force were we to contemplate departing from the *Wellcome* decision and deciding claims for methods of medical treatment should be allowed, it is of less weight on the narrower question as it has been distilled. That is essentially an issue of interpretation of the novelty requirement in light of developments internationally and is no more significant than many of the developments made by a flexible approach to the concept of patentable invention. The Courts have maintained its relevance through nearly four centuries and have been left to do

so. The issue was resolved in favour of patentability by decision in Switzerland and in the European context. It has similarly been resolved by Court decisions in England as will be reviewed below. We are not persuaded that we should defer to the legislature if otherwise satisfied that to uphold the Commissioner and Gallen J is appropriate.

[40] It would represent no greater development in the scope of patentable subject-matter than many recognised by judicial decision over the years, and we know that public interest implications are not perceived as adverse because of reform proposals formulated by the Ministry of Commerce but on hold pending resolution of certain (unrelated) issues before the Waitangi Tribunal. One proposal recommended was that there should be no specific exclusion from patentability: Ministry of Commerce, "Reform of the Patents Act 1953: proposed recommendations" (February 1992).

[41] One of the difficulties is the manner in which the case comes before us. It is a case not so much about what constitutes invention as about the requirement of novelty. That is a matter for case by case consideration yet we have no specific case before us. It is necessary to proceed on the basis of hypothetical prior publication whereas in any particular case the precise disclosure will be critical. With that in mind we postulate a second new and inventive pharmaceutical use with prior publication of a different pharmaceutical use of the same formulation or composition (if the prior known formulation or composition were different there would be novelty under present practice). This provides focus for the English decisions heavily relied on by Mr Miles for Pharmac.

[42] In *John Wyeth & Brother Ltd's Application* [1985] RPC 545 a Full Court of the Patents Court considered applications with claims in the Swiss form against the provisions of the Patents Act 1977 (UK). The relevant provisions were in terms corresponding to those in the EPC. The Court (Whitford and Falconer JJ, two vastly experienced Judges in the field) referred first to the previous practice at p 564:

> "Indeed, as the principal examiner pointed out in his Wyeth decision, the UK Patent Office has always allowed claims to a known drug formulated for a second medical use provided that the formulation claimed was novel and not obvious in view of the first (known) medical use. But the difficulty arises when the medicament or pharmaceutical agent to be manufactured is not novel and neither the Wyeth claims nor the Schering claims in the Swiss form and now under consideration specify any novelty in the agent or medicament to be manufactured. In each case the applicants' invention is based on the discovery of a new and unexpected therapeutic activity of the known compounds, already known, or some of them known, for other therapeutic activity, and the novelty and inventive step of the claimed invention must lie in that aspect of the claim."

[43] The Court first considered the application of the statutory provisions without regard to the position under EPC at p 565:

> "However, that stated, had the matter to be considered on the wording of sections 1 to 4 of the UK statute (the 1977 Act) and without regard to the position, as it has developed, under the corresponding provisions of the EPC, we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself novel, for a second or subsequent and novel

medical use would not be patentable as lacking the required novelty. It has to be recognised that it would have been a simple matter to provide for the patenting of such an invention directed to a second medical use by the omission of the word 'any' in section 2(6), if it had been the intention of the legislature that a novel second or further use of a known pharmaceutical should be patentable."

[44] However, after considering the *Eisai* decision of the enlarged Board of Appeal of the EPO, they concluded at p 567:

"That approach to the novelty of the Swiss type of use claim directed to a second, or subsequent, therapeutic use is equally possible under the corresponding provisions of the 1977 Act and, notwithstanding the opinion expressed earlier as to the better view of the patentability of such a Swiss type claim under the material provisions of the Act considered without regard to the position, as it has developed, under the corresponding provisions of the EPC, having regard to the desirability of achieving conformity, the same approach should be adopted to the novelty of the Swiss type of claim now under consideration under the material provisions of the Act."

[45] The aspect of this decision emphasised by Mr Miles was a comment upon eligibility of claims in the Swiss form under the previous Patents Act 1949 (UK) which was the basis for the New Zealand Act. The Court made it clear that on the authorities under the former Act the claims in the Swiss form would not have been allowed. Those authorities were *Adhesive Dry Mounting Co Ltd v Trapp & Co* (1910) 27 RPC 341 and *Ciba-Geigy AC (Durr's) Applications*. Those decisions strictly are not binding on us but they are well-established authorities reflecting principles that have guided practice in this country. In the *Adhesive* case a claim construed as directed to a product no different from that disclosed in a prior patent could not be allowed even though for a new use. Parker J said at p 353:

"The idea of using an old material for an entirely new purpose, not being analogous to purposes for which it has theretofore been used, may be good subject-matter, but such idea, however ingenious, can hardly justify a claim for the material itself."

[46] In *Ciba-Geigy* a new use for a known herbicide was held incapable of supporting a claim directed to the compound in a container bearing instructions for the novel use.

[47] In both of those cases the claims were directed to products limited by use. The Swiss claim is not a product claim. It is a use claim, but that use is not novel. It is known to use the active compound or composition in the making of a medicament. It is the purpose for which the medicament is made that is novel. But the manifesting of that purpose (method of treatment) cannot be included in the claim. The Court in *Wyeth* seems to have reasoned that just as specifying the purpose of a known product, even with instructions for use, was considered insufficient to provide the required novelty, so specifying the purpose for the product of a known use would have been insufficient under the same principle.

[48] In *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253 Jacob J expressed even greater reluctance in following the *Eisai* decision. He was required to rule on the validity of claims in the Swiss form directed to an invention arising from the discovery of new efficacy of a known anti-cancer chemical. His decision in the particular case was that the patent was

invalid for want of novelty and obviousness on the ground that it was not a case of second and new medical use but simply involved discovery and disclosure of more information about a known use. A similar decision had been reached by the Court of Appeal of the Hague. However, Jacob J took the opportunity to comment on the *Eisai* decision and the later decision of the enlarged Board of Appeal of the EPO in *Mobil/Friction reducing additive (Decision G02/88)* [1990] Official Journal EPO 93. He did not mince words:

> "In my view it is essential for the granting authority to consider fully the implications of the claims it grants in relation to both validity and scope. It is not helpful to take a view on validity (particularly novelty) which simply leaves intractable problems for an infringement court – and for the public who need to know what they can and cannot do.
>
> There are obvious difficulties with *Eisai*. Take a newly discovered use for aspirin (one was discovered not so long ago, namely its use to reduce risks of heart attacks). The manufacture of aspirin pills is old. So why is the manufacture rendered new because there is a new use? Or why does adding the purpose of the manufacture of aspirin to the claim make the manufacturing process any newer? (p 272)
>
> . . .
>
> I should only add that it is apparent that the decision in *Mobil* is causing considerable difficulty to national courts. It is not good enough for these difficulties to be brushed aside, as for instance was done by Mr Paterson (a member of the *Mobil* Enlarged Board) in extra-judicial lectures (to the 7th European Patent Judges Symposium (1996) 27 IIC 179) and in an article in the European Intellectual Property Review ([1991] 1 EIPR 16). Substantive European patent law demands a holistic approach to infringement and validity. . . . I hope that the EPO will find a way of convening a fresh Enlarged Board (ideally including judges with experience of infringement) to reconsider *Mobil*. After all *Mobil* seems to have no parallel in other jurisdictions, such as the USA. One way might be for the President of the EPO to decide (under Art 112(1)(b)) that different Boards of Appeal have given different decisions on the question of law – as indeed submitted by Mr Waugh in his submission concerning the *American Cyanamid* and *ICI* cases. In so saying, I am of course aware of the policy reasons behind *Mobil* (and that in *Eisai*), namely encouragement of research. But it may well be that it is not for patent law to be distorted with recourse to devices and sophistry. There are, after all, other ways of such encouragement" (p 280).

[49] Jacob J nevertheless determined he should not "go into the correctness" of these decisions and accepted, as had the Court in *Wyeth*, that novelty may rest on disclosure for the first time of a newly discovered technical effect even though a method of treatment could not be claimed.

[50] Those views demand careful consideration though the House of Lords appears to have acquiesced in the *Mobil* decision, see *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76 at p 91. We are not called on to consider those cases nor whether they are distinguishable from that before us.

[51] We have not been persuaded that there is anything in the New Zealand Patents Act or in the judicial decisions of this country which directly precludes a similar process of reasoning to that adopted in *Eisai*. We reject the contention that that decision was dictated by provisions of the EPC which are to be distinguished from the position in New Zealand.

[52] As already indicated, the law and practice on patentability in New Zealand is little different from that provided for in the EPC. Claims to methods of medical treatment are precluded. New methods of treatment of the human body now are recognised as inventions and may be claimed except in areas of diagnosis and therapy. Product claims for inventions arising from the discovery of a first pharmaceutical use for known substances are allowed.

[53] The difference lies in where novelty is perceived to reside. Under art 54(5) novelty may be in the new use whereas under our practice (and pre-1977 British practice) novelty must be found in the product formulation. However, this distinction seems blurred where first pharmaceutical use claims are permitted in forms such as "a pharmaceutical composition [of the known compound]" or "a pharmaceutically pure form [of the known compound]" which really focus on the new (pharmaceutical) use.

[54] In fact it is difficult to discern any reason why, even under the 1949 Act, the English Courts, if so persuaded, could not have moved to recognise novelty where it truly lies, in the newly discovered use. The House of Lords seems to have come close to that in the area of selection inventions. In *E I Du Pont de Nemours & Co (Witsiepe's) Application* [1982] FSR 303 at p 309 Lord Wilberforce described the development of the law regarding selection patents whereby product claims will be allowed for chemicals selected from a class already described in a prior publication if there have been discovered "unrecognised advantages" in the selected substances. This was acknowledged as a departure from the general rule that discovery of a new use or previously unrecognised advantage or quality of a known substance does not give rise to a patent. In that case the claim allowed did not specify the newly discovered advantages (use) of the substances but plainly that was where the novelty lay. Lord Wilberforce expressed his conclusion in this way at p 311:

> "Applying the law as I have endeavoured to state it, I have no doubt that the invention made by Du Pont was not disclosed or published by ICI. The latter merely indicated that the use, with other ingredients, of one preferred glycol would produce a compound with particular qualities, suggesting at the same time that use of any one of the other eight glycols would produce the same result. There was no statement that any of these others had in fact been used or that the product resulting therefrom had been found to have any particular advantages. That left it open to Du Pont to select one of them, to exercise upon it inventive research, and to discover that the product so made had valuable properties in a different field. I do not therefore understand how it can be claimed that this product, with its advantages, had been anticipated by ICI."

[55] The same difficulties of concern to Jacob J and reflected in his aspirin example would seem to apply to the grant of a selection patent.

[56] If a special doctrine was capable of formulation by the Courts to enable recognition of inventiveness in discovering new properties in substances of a class previously disclosed, so too could there have been formulated a doctrine to recognise the inventiveness in identifying new advantageous properties of known compounds and permitting claims limited to avoid interference with the practice of diagnosis and therapy.

[57] In the *NRDC* case the inventiveness lay in the discovery of the previously unrecognised property (the selective toxicity) of the known herbicide. The novelty was in the new use. Because it was non-medical, method

claims were allowed, but it is not difficult to see the analogy to the aspirin example. Is the user simply using the known herbicide for its known purpose or for the new selective kill purpose?

[58] The *Adhesive Dry Mounting* case is not authority for the proposition that a new use for a known object or substance cannot be patented. Nor is it authority for the proposition that it is insufficient to assert novelty solely in a new result of use of a known object or substance. It supports those propositions so far as they are applied to claims to the product or substance as Parker J emphasised, though selection patents represent a departure. Claims to methods by which the new result is achieved are in a quite different category as the *NRDC* case makes clear.

[59] As already mentioned, the Swiss-type claim is a use claim not a product claim. It is directed to use in manufacture for a purpose eg use of a known pharmaceutically active chemical compound plus a suitable carrier in the manufacture of a new cancer treatment medicine.

[60] It is not a product claim because a combination of the active compound and the carrier not made for the purpose of producing a cancer treatment medicine would not infringe. Nor would sale of the combination for other purposes. It is akin to a method claim – a method by which the newly discovered properties of the active compound can be exploited – and an essential element in the use is the intended end result – as it was in the application of the selective herbicide in *NRDC*. That all within the claim is known save for one element is not invalidating. Nor is the fact that the inventiveness is in the idea with its reduction to practice simple: *Hickton's Patent Syndicate v Patents and Machine Improvements Co Ltd* (1909) 26 RPC 339 at p 347. There is novelty because it cannot be said in view of the purpose element that carrying out the prior disclosure inevitably involves doing something within the claim.

[61] Infringement depending on the state of mind or purpose of the alleged infringer is not unknown to the patent law. An example is the exclusion from infringement for the benefit of those practising the invention for the purpose of bona fide research: *Monsanto Co v Stauffer Chemical Co (No 1)* (1984) 1 NZIPR 518 at p 531. Similarly in *Pfizer Corporation v Ministry of Health* [1965] RPC 261 the House of Lords considered whether the importation and sale of patented drugs for the purpose of supplying NHS hospitals fell within the exclusion from infringement as for the services of the Crown.

[62] In *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* Lord Hoffmann commented on the difficulties of establishing infringement of a patented invention the novelty of which resides only in the new purpose. He recognised at p 91 that in such a case "a person may only be working the invention when he is using it for the patented purpose".

[63] In the field of pharmaceuticals the perceived "intractable problems for infringement" referred to by Jacob J may be more apparent than real. Under the Medicines Act 1981 the manufacture and sale of medicines is closely regulated. The development, trialing, registration, manufacture and distribution of a medicine will be unlikely to give rise to difficulties in identifying the purpose for which it is intended.

[64] Just as there can be invention and novelty in the discovery of unrecognised properties in known substances qualifying for patent protection under the doctrine of selection patents and under the decision in *NRDC*, so there can be invention and novelty in the discovery of unrecognised properties of known pharmaceutical compounds. Where the somewhat special requirements for a selection patent are not met, a claim to the substance per se

should not be available. Where the new properties are employed in a method of medical treatment, claims cannot extend to that method. But by its accession to the TRIPs Agreement New Zealand has undertaken to make available patents "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (art 27:1). That obligation, which has been assumed by all parties to the agreement, is not to be set aside on grounds based on circumstances of convenience such as the comparatively low level of medical research undertaken in this country or the particular method by which medicines are funded.

[65] Once it is accepted that there can be new invention in the discovery of previously unrecognised advantageous properties in a chemical compound, the obligation to make patent protection available must apply. The provisions of the Patents Act should if possible be construed so as to give that effect. The Judge-made rules relating to novelty and methods of treatment, unless dictated by the statute, should be modified if that is necessary. Bearing in mind the rationale for the method of treatment exception permitted under the TRIPs Agreement, art 27:3 – that there should be no interference with the medical practitioner's diagnosis and treatment of patients – perhaps the logical approach would be to permit claims to extend to the method of treatment using the compound or composition but to require from the patentee a disclaimer of any right to sue the practitioner. That would leave vulnerable as indirect infringers those providing the product for the purpose of that treatment: *Innes v Short and Beal* (1898) 15 RPC 449. Essentially the same situation will be achieved by allowing claims in the Swiss form. In such a claim the integer representing the inventive subject-matter and novelty is the new use for which the medicament is made. In this particular field where that cannot be captured with a method claim, we would accept the designation of purpose as sufficient. In this way the somewhat anomalous distinction between first and second pharmaceutical uses will no longer apply and the international obligation will be satisfied.

[66] It must be emphasised that, because of the manner in which this matter has come before us, we have proceeded upon assumptions of inventiveness in the discovery of the further pharmaceutical use and lack of anticipation of that use. Those are matters to be considered on a case by case basis.

[67] For the reasons given, which differ in some respects from those of Gallen J, we would dismiss the appeal and affirm the declarations he made.

[68] The Commissioner is entitled to costs in this Court to be paid by Pharmac. These are fixed at $10,000 plus disbursements to be approved, if necessary, by the Registrar. The other respondents should meet their own costs.

Appeal dismissed.

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Solicitors for the Commissioner: *Solicitor, Ministry of Commerce* (Wellington).

Solicitors for Glaxo Group Ltd, Astra AB and others: *A J Park & Son* (Wellington).

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Reported by: Graeme Jenkins, *Barrister*